Food and Drug Administration
Center for Food Safety and Applied Nutrition
Office of Special Nutritionals

ARMS#

12462

0 - FRONT

[redacted]

COMPLAINT/INJURY REPORT

1. COMPLAINT NUMBER: FLA-8747 12462
2. DATE OF COMPLAINT (Month/Day/Year): 7/8/97

3. FORM OF COMPLAINT
(1) XX TELEPHONE
(2) ☐ LETTER
(3) ☐ VISIT

4. SOURCE OF COMPLAINT
(1) XX CONSUMER
(2) ☐ GOVERNMENT ☐ L ☐ S ☐ F
(3) ☐ TRADE SOURCE
(4) ☐ OTHER (Indicate in Remarks)

5. COMPLAINANT IDENTIFICATION
a. NAME AND ADDRESS (Include Zip Code): [redacted]
b. AREA CODE AND TELEPHONE NUMBER
HOME [redacted]
WORK

6. COMPLAINT OR INJURY
a. DESCRIPTION OF COMPLAINT/INJURY
Complainant stated that her son had taken four capsules of the product and exp experienced tremors, tingling all over, couldn/t sleep, and felt like he was going to pass out. Her son has seen a physican and cardiologist. An EKG was performed and was abnormal.

b. DOES COMPLAINANT EXPECT ADDITIONAL FDA CONTACT?
(1) XX NO (2) ☐ YES (Explain in Remarks)

7. INJURY OR ILLNESS RESULTED
(1) ☐ NO
(2) XX YES
(If "yes" complete items a through d)

a. EIB (HFC-167) NOTIFIED
(1) ☐ NO
(2) XX YES
DATE 7/8/97

b. TYPE SYMPTOMS — ONSET (HR.)
1. ☐ VOMITING
2. ☐ NAUSEA
3. ☐ DIARRHEA
4. ☐ FEVER
5. ☐ SKIN/EYE IRR.
6. ☐ HEADACHE
7. XX OTHER 3 hours
[redacted] ~~tingling, tremors~~, insomnia, ~~and felt like going to pass out~~

c. ATTENDING HEALTH PROFESSIONAL
(1) ☐ NO (2) XX YES
(If "yes" give name, address, and phone number)
phy: [redacted]
cardi: DR. unknown at this time

d. HOSPITALIZATION REQUIRED
(1) XX NO (2) ☐ YES
(If "yes" give name, address, phone number and dates)

8. PRODUCT AND LABELING
a. BRAND NAME: GNC
b. PRODUCT NAME: Ripped Fuel
c. SIZE AND PACKAGE TYPE: 60 caps plastic bottle
d. NAME AND LOCATION OF STORE WHERE PURCHASED: [redacted]
e. PACKAGE CODE/SERIAL NUMBER/ETC.: 6A170 or GA170
EXP/USE BY DATE:
f. DATE PURCHASED: o/a 6/16/97
g. PRODUCT USED (If "yes" enter date) (1) ☐ NO (2) XX YES
h. AMT REMAINING: all but 4

9. MANUFACTURER/ DISTRIBUTOR OF PRODUCT
a. HOME DISTRICT: New York
b. C.F. NO.: 2421049
c. NAME AND LOCATION OF FIRM (Include Zip Code): labeled as: Twin Labs Ronkonkoma, NY 11779
d. IMPORT PRODUCT (1) XX NO (2) ☐ YES

10. EVALUATION AND DISPOSITION
a. PROBLEM KEYWORD (1) CODE: RX (2) DESCRIPTION: reaction
b. EVALUATION
(1) ☐ NOT AN FDA OBLIGATION
(2) ☐ OBLIGATION, NO VIOLATION
(3) ☒ FDA ACTION INDICATED
(4) ☐ INSUFFICIENT INFORMATION UNABLE TO EVALUATE
c. DISPOSITION
(1) ☐ IMMEDIATE FOLLOW-UP
(2) ☐ F/U NEXT EI
(3) ☐ CLOSED WITHOUT FURTHER INVESTIGATION
(4) ☐ REFERRED TO OTHER FEDERAL AGENCY (Closes File)
(5) ☐ REFERRED TO STATE/LOCAL AGENCY (Closes file)
(6) XX REFERRED TO OTHER FDA NY DISTRICT

11. PRODUCT CODE: 54YCA99

12. INFORMATION COPIES TO;
☐ HFB-100 ☐ HFZ-343
☐ HFD-730 ☐ HFC-161
☐ HFV-236 XX faxed to HFS-635 (202)205-9670
ATTENTION: ARMS MONITOR

REMARKS

NAME AND TITLE: Julie D. Bringger, Investigator
DATE: 7/8/97

FORM FDA 2516 (1/90)

*U.S. GPO: 1992-312-208/61

Memo 10/28/97
Subject FIROU assignment #07442
Attachment 4 page
Joe

Adverse Reaction Information Form A

Complaint Number: FA-8747 Investigator: Julie D. Bringger

Consumer Information

Date of Report: 10/16/97* MM/DD/YY *followup date	Initial Report Source: ■ORA Consumer Injury □Telephone □Correspondence □MedWatch □USP □PQRS □Poison Control □CDC
Name: [redacted]	Gender: □F ■M Age: 20 yrs

Race: ■1-White □2-Black □3-Asian/Pacific Islander □4-Native American □5-Hispanic □8-Other ________ □9-Unknown

Information on Adverse Reaction

Date of Adverse Reaction: O/A 6/21/97
Previous Reaction to Product Type: □Yes ■No

Give the site of consumption/ingestion (e.g. home, restaurant, office): home

Describe the adverse event (including symptoms and the time lapse from using product to onset of symptoms): Symptoms began on Sunday following ingestion of product 4 separate occassions. Felt like going to pass out, numbness, blacking out, tremors.

How long did the symptoms last? 1 week after discontinuing the product

Give the circumstances of exposure (e.g., dose, route of exposure, frequency, etc.). Took 2 tabs on a Thursday, To 2 tabs the following Friday, Took 2 tabs Saturday morning and then 2 tabs 2 hours later

List all Medication(s), Dietary Supplement(s), Food(s), and other product(s) used at the time of the event: -nothing other than possibly Vitamin C. - had eaten turkey sandwich for lunch.

Did event abate after use of suspected product stopped or dose reduced: □Yes ■No □Unknown

Did symptoms reoccur after reintroduction of suspected product: □Yes □No □Unknown ■Not Applicable

Did symptoms reoccur after using other products with the same ingredients: □Yes □No ■Unknown □Not Applicable

Medical Information

Was a health care provider seen?: ■Yes □No

Give health care provider's name, address and telephone number: [redacted]

Occupation of Health Care Provider: ■MD □Osteopath □Naturopath □Nurse □Pharmacist □Other (specify) ________

What medical tests were performed and what were the results?

What was the medical diagnosis? SEE MEDICAL RECORDS

What treatment(s) was given (e.g., drugs, other)?

Were there any preexisting condition(s)/treatment(s)?
(If YES, list them including allergies, and chronic diseases): □Yes ■No

Product Category

1. Adverse reaction to:
   □**Medical Food** (under medical supervision) □**Infant Formula**
   ■**Dietary Supplement** (a vitamin; an essential mineral; a protein; a herb or similar nutritional substances including botanicals such as ginseng and yohimbe; amino acids; extracts from animal glands; garlic extract; fish oils; oil of evening primrose; fibers such as psyllium and guar gum; compounds not generally recognized as food or nutrients, such as bioflavonoids, enzymes, germanium, nucleic acids, para-amino-benzoic acid, and rutin; and mixtures of these ingredients.)
   □**Other** (traditional food) ________

<u>Other Product Problems</u>

2. □Foreign Object (specify): ________
3. □Other (specify): ________

000002

Memo: 10/24/97
Subject: FRADU assignment 010417
503
Attachment # 2

Information on Suspected/Alleged Product

Give the product name (including dose/serving size, duration of use, and reason for taking):
TWINLAB METABOLIC ENHANCER RIPPED FUEL

– SEE LABELING FOR dosage, duration

List product ingredients (if ingredients are suspected to be present, but not verified, list as suspected):
☐Check here if ingredients are unknown
Mahuang Extract, Guarana Extract, L-Carnitine, Chromium

If a particular ingredient is suspected of contributing to the reaction, please indicate the appropriate category below:

☐Aspartame ☐Color Additive (please specify) ____________
☐Monosodium Glutamate
☐Sulfite
☐Other ____________
☐Unknown

Product Label Available: ■Yes* ☐No ☐Unknown Product Sample Available: *■Yes ☐No ☐Unknown
obtained copy of label *Can get spl of product if warranted

Outcome Attributed to Adverse Event:

(If yes, include pertinent medical records)

Death: ☐Yes ■No

Life-Threatening: ☐Yes ■No (SEE MEDICAL RECORDS)

Hospitalization: ☐Yes ■No (if YES, indicate if initial or prolonged) ____________

Required intervention to prevent permanent impairment/damage: ☐Yes ■No

Did the adverse reaction result in a congenital anomaly: ☐Yes ■No

DEPARTMENT OF HE TH & HUMAN SERVICES — Public Health Service

Memorandum

Food and Drug Administration

Date: October 24, 1997

From: Billie D. Bringger, Investigator [redacted]

Subject: Florida district assignment #970417 - Ripped Fuel
FIRM: Twin Laboratories, Inc.
Ronkonkoma, NY 11779
CIN: 2421049

To: Terry G. Forrest, Supervisory Investigator
Florida District Office

This memorandum documents FLA-DO's follow-up to the subject assignment (Attachment 1) which originated from CFSAN, Division of Field Program Planning and Evaluation. Referenced assignment involved the collection of medical records, completion of an adverse event questionnaire, and product labeling regarding FLA-DO complaint #FLA-8747. A copy of the assignment and the complaint is included as Attachment 1.

On 10/16/97, an authorization for medical records disclosure was obtained from the complainant's son and subsequently delivered to the family physician's office for processing. I explained to the physician's office that I needed records pertaining to a visit made on or around 6/16/97. Records pertaining to a 6/24/97 visit were provided and are included as Attachment 2.

To: Ronald R. Roy, CFSAN, HFS-636, Domestic Programs Branch, Division of Field Program Planning and Evaluation

Requested information is attached.

Terry G. Forrest

Terry G. Forrest, SI
FLA-DO

cc: [redacted]
: PRD

Rcvd 11/14/97
RRR

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NOV 14 1997

97 NOV 18 A8:55

RECEIVED
CLINICAL RESEARCH
& REVIEW/OSN HFS-452

Labeling was obtained via purchase of one product container from the store the original product was purchased from. After the labeling was copied the product was field destroyed. The labeling is included as Attachment 3. The adverse event questionnaire was completed at the same time the authorization for medical records was obtained. The completed adverse event questionnaire is included as Attachment 4.

Julie D. Bringger

Julie D. Bringger, ZO3
Investigator, [redacted]

ATTACHMENTS 1-4

final: 11/4/97/jdb